

Statistical Analysis Plan

Development and Pilot Testing of a Multimodal Web-based Program to Address Heavy Drinking
During Smoking Cessation

NCT03068611

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To assess feasibility of study procedures in this pilot randomized controlled trial, we will first examine the number of participants passing study milestones (e.g., screening, consent, baseline, follow-up) and the baseline characteristics of the sample. Acceptability of EX-HD will be examined by comparing EX-S and EX-HD on website and text message utilization and program satisfaction using *t*-tests and non-parametric tests for non-normally distributed data such as the number of website visits.

We will examine the preliminary efficacy of EX-HD by comparing smoking and alcohol use outcomes between EX-HD and EX using *t*-tests and chi-square tests. To account for the repeated assessment of alcohol and smoking outcomes over time and variables included in the randomization scheme, we will conduct negative binomial and logistic regression analyses using generalized estimating equations (GEE) that covary age, sex, and baseline frequency of heavy drinking. The primary smoking outcome is self-reported 7-day point prevalence smoking abstinence. Missing data on this variable will be treated as non-abstinence consistent with conventions in the field. The primary drinking outcome is a count variable, number of heavy drinking days at 1 and 6 months. Therefore, a negative binomial model will be used. These analyses will use all available data. Because of small sample size, multiple imputation approaches will not be used. Because there are only two repeated assessments in the GEE models (1 and 6 months), a compound symmetric correlation structure will be used to account for clustering of data over time.

We will use chi-square analyses to test whether EX-HD reduced the odds of alcohol-involved smoking lapses compared to EX-S and whether lower odds of alcohol-involved lapses is associated with better smoking outcomes at 1 and 6 months.

Exploratory analyses will examine whether treatment effects are moderated by gender and motivation to change (i.e., perceived importance of quitting smoking and of reducing drinking, respectively) and whether the effect of EX-HD differed based on level of website engagement and text messaging enrollment. Moderation effects are tested by creating product terms between intervention condition and the respective moderator and adding that term to the main effects model in the GEE analyses.